

### **REMARKS**

The non-final Office Action of June 18, 2003 has been received and carefully considered. Prior to this Office Action, claims 1-72 were pending in the present application. Of these claims, claims 26-45, 53-63, and 68-72 have been withdrawn from consideration. By the present amendment, withdrawn claims 26-45, 53-63, and 68-72 are canceled. Accordingly, claims 1-25, 46-52 and 64-67 are pending for further consideration. In view of the reasons discussed herein, Applicant respectfully submits that the these pending claims are in condition for allowance.

#### **I. Claim Objections**

Claims 4, 9, and 11 are objected to as being dependent upon a rejected base claim. Applicant, however, acknowledges with appreciation the Examiner's indication that these claims would be allowable if rewritten in independent form to include all limitations of the base claims and an intervening claim. In view of the reasons to follow, Applicant submits that the base claim upon which these claims depend is in condition for allowance, such that the proposed rewriting of these claims is unnecessary.

#### **II. Claim Rejection Under 35 U.S.C. 102(b) in view of U.S. Patent No. 5,260,222 to Patel et al.**

Claims 1-2, 5-7, 10, 12-13 and 64-67 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure of U.S. Patent No. 5,260,222 to Patel et al. (hereinafter "Patel et al.") For the reasons discussed below, Applicant respectfully disagrees.

First, with respect to Patel et al., it is argued in the Office Action that:

Patel et al. teaches a device (10) that has ports (12) that permit fluid to the bottom of the device. There is a first piece of bibulous material (32), and a second piece of bibulous material (34) and a piece of liquid expandable material (22). When material (28) expands, materials (32) and (34) are in fluid contact with one another. Material (28) expands as a result of fluid through port mark (20). Material (28) has been read on the claimed "expandable collection device." Material (34) can act as a reagent for analysis of a reagent.

See, Office Action, page 2.

Applicant respectfully submits, however, that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or

inherently described, in a single prior art reference.” *Verdegall Bros. v. Union Oil Co. of California*, 2 USP2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim” *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In the present case, Patel et al. fail to teach each and every aspect of the claims 1-2, 5-7, 10, 12-13 and 64-67, as required under 35 U.S.C. 102(b).

In particular, with respect to claim 1, it is noted that Patel et al. do not teach or inherently suggest a sample collection device for assay comprising: (1) a holder portion having a first end and a second end; (2) a retaining portion coupled to the holding portion second end and selectively configurable between at least an extendable size and a contracted size; and (3) an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size, wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size. Accordingly, the invention of claim 1 is not anticipated, or otherwise render obvious, by the teachings of Patel et al.

Notwithstanding the fact that each of claims 2, 5-7, 10, 12-13 are dependent on claim 1, and as such are deemed to include each and every element of claim 1, Applicant submits that Patel et al. also fail to teach those elements specifically recited in these dependent claims. Accordingly, these claims are also not anticipated, or otherwise rendered obvious, by Patel et al.

With respect to independent claim 64, it is respectfully submitted that Patel et al. also do not teach or inherently suggest a method for collecting a sample adequate for assay comprising the steps of: (1) providing a sample collector for collecting sample, the sample collector having a second size when a sufficient sample for assay is contained in the sample collector and a first size when an insufficient sample for assay is contained in the sample collector; (2) providing a collector holder, the collector holder including a sample area for indicating whether the sample collector has collected a sample sufficient for assay, the sample area defining a sample adequacy size; (3) disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area; (4) collecting a sample on the sample collector; and (5) comparing the size of the sample collector to the sample adequacy size and if the sample adequacy size is approximately equal

to the second size then an adequate sample is collected for assay. Accordingly, Petal et al. do not anticipate, or otherwise render obvious, the invention of claim 64.

Notwithstanding the fact that each of claims 65-67 are dependent on claim 64, and as such are deemed to include each and every element of claim 64, Applicant submits that Patel et al. also fail to teach those elements specifically recited in these dependent claims. Accordingly, these claims are also not anticipated, or otherwise rendered obvious, by Patel et al.

### **III. Claim Rejection Under 35 U.S.C. 102(b) in view of U.S. Patent No. 5,198,193 to Bunce et al.**

Claims 1-2, 5-7, 10, 12-13 and 64-67 are also rejected under 35 U.S.C. 102(b) as being anticipated by Bunce et al. In particular, it is contended that Bunce et al. teach many different configurations that read on the instant claims. Figure 4, in particular, is noted as being exemplary. According to the Office Action, Figure 4 teaches a liquid transfer device comprising holding portion (70d) having a first and second ends, a retaining portion (32) attached to the holding portion, and expandable collection member (23d) having a first and second size and reagents (32d) to detect the analyte of interest.

Applicant respectfully submits that Bunce et al. also fail to teach or inherently suggest each and every element of claims 1-2, 5-7, 10, 12-13, and 64-67. In particular, with respect to claim 1, it is noted that Bunce et al. do not teach or inherently suggest a sample collection device for assay comprising: (1) a holder portion having a first end and a second end; (2) a retaining portion coupled to the holding portion second end and selectively configurable between at least an extendable size and a contracted size; and (3) an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size, wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size. Accordingly, Bunce et al. does not anticipate, or otherwise render obvious, the invention of claim 1.

Notwithstanding the fact that each of claims 2, 5-7, 10, 12-13 are dependent on claim 1, and as such are deemed to include each and every element of claim 1, Applicant submits that Bunce et al. also fail to teach those elements specifically recited in these dependent claims. (Moreover, with reference to FIG 4, applicant notes that the item "70d" is

misdescribed as a “holding portion” when it is clearly described as a “channel” in the specification and claims (*See*, Bunce et al., Col. 4, lines 61-64; claim 1)). Accordingly, these claims are also not anticipated, or otherwise rendered obvious, by Bunce et al.

With respect to independent claim 64, it is respectfully submitted that Bunce et al. also do not teach or inherently suggest a method for collecting a sample adequate for assay comprising the steps of: (1) providing a sample collector for collecting sample, the sample collector having a second size when a sufficient sample for assay is contained in the sample collector and a first size when an insufficient sample for assay is contained in the sample collector; (2) providing a collector holder, the collector holder including a sample area for indicating whether the sample collector has collected a sample sufficient for assay, the sample area defining a sample adequacy size; (3) disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area; (4) collecting a sample on the sample collector; and (5) comparing the size of the sample collector to the sample adequacy size and if the sample adequacy size is approximately equal to the second size then an adequate sample is collected for assay. Accordingly, Petal et al. do not anticipate, or otherwise render obvious, the invention of claim 64

Notwithstanding the fact that each of claims 65-67 are dependent on claim 64, and as such are deemed to include each and every element of claim 64, Applicant submits that Bunce et al. also fail to teach those elements specifically recited in these dependent claims. Accordingly, these claims are also not anticipated, or otherwise rendered obvious, by Bunce et al.

#### **IV. Claim Rejection Under 35 U.S.C. 102(b) in view of U.S. Patent No. 3,713,755 to Schmitz**

Claims 1, 3, 7-8, 10, 12-13, 64-66 and 14-25 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure of U.S. Patent No. 3,713,775 to Schmitz (hereinafter “Schmitz”). In particular, it is contended that Schmitz teaches in Figures 2-3 a pipette (51) having a first and second end. The interior of the pipette retains a sample and plunger (54) has been read on the claimed “expandable collection member” having a first and second size. The pipette tip (55) has been read on the claimed “discharge member” and place the sample in curette (36) containing reagents (210).

Applicant respectfully submits that Schmitz also fails to teach or inherently suggest each and every element of claims 1, 3, 7-8, 10, 12-13, 64-66 and 14-25. In particular, with respect to claim 1, it is noted that Schmitz does not teach or inherently suggest a sample

collection device for assay comprising: (1) a holder portion having a first end and a second end; (2) a retaining portion coupled to the holding portion second end and selectively configurable between at least an extendable size and a contracted size; and (3) an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size, wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size. Accordingly, Schmitz does not anticipated, or otherwise rendered obvious, the invention of claim 1.

Notwithstanding the fact that each of claims 2, 5-7, 10, 12-13, and 14-25 are dependent on claim 1, and as such are deemed to include each and every element of claim 1, Applicant submits that Schmitz also fail to teach those elements specifically recited in these dependent claims. Accordingly, these claims are also not anticipated, or otherwise rendered obvious, by Schmitz.

With respect to independent claim 64, it is respectfully submitted that Schmitz also does not teach or inherently suggest a method for collecting a sample adequate for assay comprising the steps of: (1) providing a sample collector for collecting sample, the sample collector having a second size when a sufficient sample for assay is contained in the sample collector and a first size when an insufficient sample for assay is contained in the sample collector; (2) providing a collector holder, the collector holder including a sample area for indicating whether the sample collector has collected a sample sufficient for assay, the sample area defining a sample adequacy size; (3) disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area; (4) collecting a sample on the sample collector; and (5) comparing the size of the sample collector to the sample adequacy size and if the sample adequacy size is approximately equal to the second size then an adequate sample is collected for assay. Accordingly, Schmitz does not anticipate, or otherwise render obvious, the invention of claim 64.

Notwithstanding the fact that each of claims 65-67 are dependent on claim 64, and as such are deemed to include each and every element of claim 64, Applicant submits that Schmitz also fails to teach those elements specifically recited in these dependent claims. Accordingly, these claims are also not anticipated, or otherwise rendered obvious, by Schmitz.

**V. Claim Rejection Under 35 U.S.C. 102(b) in view of U.S. Patent No. 4,750,373 to Shapiro; U.S. Patent No. 4,036,064 to Hydo; or U.S. Patent No. 5,364,596 to Magnussen et al.**

Claims 1, 3, 7-8, 10, 12-13, 46-51, and 64-66 are also rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure of U.S. Patent No. 4,750,373 (hereinafter "Shapiro"), U.S. Patent No. 4,036,064 to Hydo (hereinafter "Hydo") or U.S. Patent No. 5,364,596 to Magnussen et al. (hereinafter "Magnussen et al."). In particular, it is contended in the Office Action that these references teach sample collection means having a plunger with multiple positions and stops, which have been read on the claimed first and second holding positions.

Applicant respectfully submits that Shapiro, Hydo, or Magnussen et al. when taken alone or in combination, fail to teach each and every element of the claimed invention. In particular, with respect to claim 1, it is noted that Shapiro, Hydo, or Magnussen et al. do not teach or inherently suggest a sample collection device for assay comprising: (1) a holder portion having a first end and a second end; (2) a retaining portion coupled to the holding portion second end and selectively configurable between at least an extendable size and a contracted size; and (3) an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size, wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size. Accordingly, the invention of claim 1 is not anticipated, or otherwise rendered obvious, by Shapiro, Hydo, or Magnussen et al.

Notwithstanding the fact that each of claims 1, 3, 7-8, 10, 12-13, 46-51 are dependent on claim 1, and as such are deemed to include each and every element of claim 1, Applicant submits that Shapiro, Hydo, or Magnussen also fail to teach those elements specifically recited in these dependent claims. Accordingly, these claims are also not anticipated, or otherwise rendered obvious, by the teachings of Shapiro, Hydo, or Magnussen et al.

With respect to independent claim 64, it is respectfully submitted that Shapiro, Hydo, or Magnussen et al. also does not teach or inherently suggest a method for collecting a sample adequate for assay comprising the steps of: (1) providing a sample collector for collecting sample, the sample collector having a second size when a sufficient sample for assay is contained in the sample collector and a first size when an insufficient sample for assay is contained in the sample collector; (2) providing a collector holder, the collector

holder including a sample area for indicating whether the sample collector has collected a sample sufficient for assay, the sample area defining a sample adequacy size; (3) disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area; (4) collecting a sample on the sample collector; and (5) comparing the size of the sample collector to the sample adequacy size and if the sample adequacy size is approximately equal to the second size then an adequate sample is collected for assay. Accordingly, Shapiro, Hydo, or Magnussen et al. do not anticipate, or otherwise render obvious, the invention of claim 64

Notwithstanding the fact that each of claims 65-66 are dependent on claim 64, and as such are deemed to include each and every element of claim 64, Applicant submits that Shapiro, Hydo or Magnussen et al. also fail to teach those elements specifically recited in these dependent claims. Accordingly, these claims are also not anticipated, or otherwise rendered obvious, by Shapiro, Hydo, or Magnussen et al.

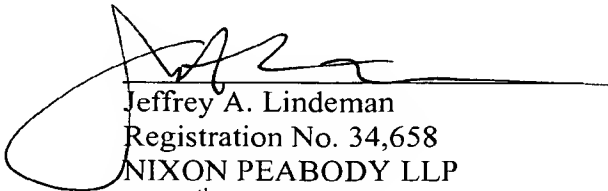
### III. Conclusion

In view of the foregoing, Applicant submits all of the cited references, whether taken alone or combined, fail to teach, suggest, or render obvious each and every aspect of the claimed invention. Accordingly, it is respectfully submitted that claims 1-3, 5-8, 10, 12-25, 46-52, and 64-67 should be reconsidered and withdrawn.

Having responded to each and every rejection set forth in the Office Action, it is respectfully submitted that the application should now be in condition for allowance. Accordingly, an early Notice of Allowance is courteously requested. Should there be any outstanding issues to be resolved, the Examiner is invited to contact the undersigned by telephone to expedite the prosecution of the case.

Respectfully submitted,

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